

October 3, 1997

**MEDICAID CLINICAL LABORATORY IMPROVEMENT  
AMENDMENTS (CLIA)IMPLEMENTATION**

**RELEASE No. 32**

Dear State Medicaid Director:

**PLEASE CONVEY TO MEDICAID CLAIMS PROCESSORS IMMEDIATELY!**

In Medicaid CLIA Release no. 31 all Medicaid State Agencies (MSAs) were instructed to deny payments to all laboratories submitting claims for services not covered by a CLIA certificate and for all claims for services rendered outside effective dates of a CLIA certificate beginning with claims processed on or after January 1, 1998. MSAs have a window of six months starting with January 1 to initiate the action to deny those payments. This letter is to clarify instructions contained in CLIA Release no. 31 and provide new processing procedures for updating CLIA files.

As indicated in CLIA Release no. 31, all laboratories will be affected by CLIA claims processing editing which includes editing all claims for:

- labs which do not have a CLIA certificate,
- labs submitting claims for services not covered by CLIA certificate, and
- labs submitting claims for services rendered outside the effective dates of the CLIA certificate.

We have 3 clarifying instructions. First, denial of claims for tests submitted by laboratories which are not approved under the laboratory's current CLIA certificate (second point above) are to be made according to the type of certificate held by the laboratory. Second, laboratories with waiver certificates can bill only for tests listed in Attachment A and laboratories with a provider-performed microscopy procedure (PPMP) certificate can bill only for tests listed in Attachments A and B. Third, at this time, claims for tests performed under a regular (Certificate of Compliance), partial accredited (combination of Certificate of Compliance and Certificate of Accreditation), accreditation (Certificate of Accreditation), or registration Certificate must all be paid as long as the laboratory has an effective CLIA certificate regardless of the test performed.

We have several new processing procedures for updating the CLIA files. First, HCFA is changing the way record type 5 (MSA Specialty/Subspecialty Record) and record type 7 (MSA Proficiency Testing (HCPCS) Record) are stored in the Online Survey Certification and Reporting (OSCAR) system and subsequently sent to the MSAs using the Report 91 program and/or a replacement tape/cartridge. Presently, whenever a "code" in either of the two record types expires and then is continued with a new certificate period, a new code is created with new effective and expiration dates. This procedure creates unnecessary data on the system. The new procedure will change the expiration date of the existing code to the new extended time period. In essence, less space will be required to store the same data on the system. If a laboratory were to drop the use of a code for a period of time and then restart use of the code at a later date the system would then have codes reflecting the appropriate effective and expiration dates. The new procedure will affect records only when the expiration date changes and will begin on or after November 21, 1997.

Second, in an effort to provide necessary data to operate the Medicaid program more timely, we are testing the use of the Internet as a means to distribute pricing files. Initially, the files that can be accessed are:

1. the Clinical Lab Fee Schedule;
2. the Durable Medical Equipment, Prosthetics/Orthotic, and Supplies (DMEPOS) Fee Schedule; and,
3. the National Physician Fee Schedule Relative Value File.

All of these are listed under the heading Payment Rates -- Non Institutional Providers on the Internet at:  
"<http://www.hcfa.gov/stats/pufiles.htm>".

These self-executing compressed files also contain the layout of the data and will be in multiple formats: Excel, text, and comma delimited. Whenever updates are made the file on the Internet will be replaced. MSAs should download all of the files now to ensure that they can read and use them and should contact Medford J. Campbell, Jr. at (410) 786-4457 by mid-October 1997 if they experience any problems or have comments to improve this procedure. Since we anticipate using only the Internet to provide all of these type of files to MSAs in the future, it is imperative that this test period be used to resolve any problems.

The files presently on the Internet are for the year 1997. The 1997 Physician Fee Schedule Payment Amount File is not currently available on the Internet but it will be available at a later date. The 1998 Clinical Lab Fee file will be available November 25. The 1998 DMEPOS file will be available December 2 and the revised file to include the gap filled codes

will be available December 16. The 1998 Physician Fee Schedules will be available on November 4. Please be aware that all of these dates are subject to change if we experience unexpected problems.

Refer comments or questions to Medford J. Campbell, Jr. at (410) 786-4457 .

/s/

Charlene Brown for  
Sally K. Richardson  
Director  
Center for Medicaid and State Operations

Attachments

cc:

All HCFA Regional Administrators  
All HCFA Associate Regional Administrators for Medicaid and State Operations  
Lee Partridge - American Public Welfare Association  
Joy Wilson - National Conference of State Legislatures  
Jennifer Baxendell - National Governors' Association

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#### **Attachment A**

<b>Dipstick or tablet reagent urinalysis - non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrate, pH, protein, specific gravity, and urobilinogen</b>	<b>Various</b>	<b>81002</b>	<b>Screening of urine for diseases/conditions, or urinary tract, and</b>
<b>Fecal occult blood</b>	<b>Various</b>	<b>82270</b>	<b>Detection of blood in malignant (colorectal)</b>
<b>Ovulation tests by visual color comparison for human luteinizing hormone</b>	<b>Various</b>	<b>84830</b>	<b>Detection of ovulation</b>
<b>Urine pregnancy tests by visual color comparison</b>	<b>Various</b>	<b>81025</b>	<b>Diagnosis of pregnancy</b>
<b>Erythrocyte sedimentation</b>	<b>Various</b>	<b>85651</b>	<b>Nonspecific screening</b>

rate - non-automated			increased for major carcinoma and leuk
Hemoglobin by copper sulfate - non-automated	Various	83026	Monitors hemoglob
Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	82962	Monitoring of blood
Blood count; spun microhematocrit	Various	85013	
Screen for anemiaHemoglobin by single instrument with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout	HemoCue	85018QW (effective 10/1/96)	Monitors hemoglob should be discontin
HemoCue B-Glucose Photometer	HemoCue	82947QW, 82950QW, 82951QW, 82952QW (effective 10/1/96)	Diagnosis and moni codes G0055, G005 this test 9/30/96)
Chemtrak Accumeter	Chemtrak	82465QW	Cholesterol monitor
Advanced Care	Johnson & Johnson	82465QW	Cholesterol monitor
Boehringer Mannheim Chemstrip Micral	Boehringer Mannheim	82044QW	Monitors low conce helpful for early de disease
Cholestech LDX	Cholestech	82465QW 83718QW 84478QW 82947QW 80061QW	Monitors total chol and glucose levels
Serim Pyloritek Test Kit	Serim	87072QW	Presumptive identifi biopsy tissue, which gastritis (ulcers)

<b>Quick Vue In-Line One-Step Strep A Test</b>	<b>Quidel</b>	<b>86588QW</b>	
<b>Rapidly detects Group A streptococcal (GAS) antigen from throat swabs and used as an aid in the diagnosis of GAS infection which typically causes strep throat, tonsillitis and scarlet fever</b> <b>Boehringer Mannheim Accu-Chek InstantPlus Cholesterol</b>	<b>Boehringer Mannheim</b>	<b>82465QW</b>	<b>Cholesterol monitor</b>
<b>All qualitative color comparison pH testing - body fluids (other than blood)</b>	<b>Various</b>	<b>83986QW</b>	<b>pH detection (acid-base semen, amniotic fluid)</b>
<b>SmithKline Gastrocult</b>	<b>SmithKline</b>	<b>82273QW</b>	<b>Rapid screening test for blood</b>
<b>QuickVue One-Step H. Pylori Test for Whole Blood</b>	<b>Quidel</b>	<b>86318QW</b>	<b>Immunoassay for rapid detection of antibodies specific to H. pylori</b>
<b>Binax NOW Strep A Test</b>	<b>Binax</b>	<b>86588QW</b>	<b>Rapidly detects Group A streptococcal (GAS) antigen from throat swabs and used as an aid in the diagnosis of GAS infection which typically causes strep throat, tonsillitis and scarlet fever</b>
<b>Delta West CLOtest</b>	<b>Delta West</b> <b>Tri-Med Specialties</b>	<b>87072QW</b>	<b>Presumptive identification of H. pylori in biopsy tissue, which causes gastritis (ulcers)</b>
<b>Wampole STAT-CRIT Hct</b>	<b>Wampole Laboratories</b>	<b>85014QW</b>	<b>Screen for anemia</b>
<b>SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood</b>	<b>SmithKline Diagnostics, Inc.</b>	<b>86318QW</b>	<b>Immunoassay for rapid detection of antibodies specific to H. pylori</b>
<b>Wyntek Diagnostics OSOM Strep A Test</b>	<b>Wyntek Diagnostics, Inc</b>	<b>86588QW</b>	
<b>Rapidly detects Group A streptococcal (GAS) antigen</b>	<b>Mycoscience Labs, Inc.</b>	<b>87072QW</b>	<b>Presumptive identification of H. pylori in biopsy tissue, which causes gastritis (ulcers)</b>

from throat swabs and used as an aid in the diagnosis of GAS infection which typically causes strep throat, tonsillitis and scarlet fever  
GI Supply  
HP-FAST

gastritis (ulcers)

Abbott FlexPak HP Test for whole blood

Abbott Laboratories

86318QW

Immunoassay for r antibodies specific t

Chemtrak AccuMeter

ChemTrak

Pending

Immunoassay for r antibodies specific t

H. pylori Test (for whole blood)

BioStar Acceava Strep A Test (direct specimen only)

BioStar, Inc.

86588QW

Rapidly detects Gro throat swabs and us infection which typi scarlet fever

LXN Fructosamine Test System

LXN Corporation

82985QW

Used to evaluate dia over a 2-3 week per diabetes mellitus.

\*ITC Protime Microcoagulation System for Prothrombin Time

International Technidyne Corporation (ITC)

Pending

Aid in screening for VII, X; screen for d heparin effect, coun vitamin K deficienc

\*CoaguChek for Prothrombin Time

Boehringer Mannheim Corporation

Pending

Aid in screening for VII, X; screen for d heparin effect, coun vitamin K deficienc

\*SmithKline ICON Fx Strep A Test

Binax

86588QW

Rapidly detects Group A streptococcal (GAS) antigen from throat swabs and used as an aid in the diagnosis of GAS infection which typically causes strep throat, tonsillitis and scarlet fever\*Abbott Signify Strep A Test

Wyntek Diagnostics, Inc.

86588QW

Rapidly detects Gro throat swabs and us infection which typi scarlet fever

\* Newly-added waived test system

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**Attachment B**

**Provider-performed Microscopy Procedures  
June 24, 1997**

**Q0111 - Wet mounts, including preparations of vaginal, cervical or skin specimens**

**Q0112 - All potassium hydroxide (KOH) preparations**

**Q0113 - Pinworm examinations**

**Q0114 - Fern test**

**Q0115 - Post-coital direct, qualitative examinations of vaginal or cervical mucous**

**81015 - Urinalysis; microscopic only**

**81000 - Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy**

**81020 - Urinalysis; two or three glass test (CWF effective date 7/14/97)**

**G0026 - Fecal leukocyte examination**

**G0027 - Semen analysis; presence and/or motility of sperm excluding Huhner**

**89190 - Nasal smears for eosinophils**